





## FORWARD-LOOKING STATEMENTS

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A close-up photograph of a medical device, likely a blood purifier or dialyzer. It features a clear plastic cylindrical body with a blue cap and a yellow connector. Red and white medical tubing are connected to the device. The background is blurred, showing more of the device and tubing.

## Blood Purification Technologies to Treat Cancer & Life-Threatening Infections



## Summary

- Our lead product is positioned to address infectious disease disorders not treatable with drugs
  - Previously founded company whose infectious disease device drove peak market value of ~\$200 million on Nasdaq
  - Market comparable is a company with a clinical-stage device to treat sepsis whose market value is ~16x Sigyn Therapeutics at present
- Our pipeline is comprised of first-in-industry devices to improve delivery of leading cancer therapies



## Our Therapeutic Candidates

- **Sigyn Therapy™** to address life-threatening infections\*
- **ChemoPure™** to reduce chemotherapy toxicity
- **ChemoPrep™** to optimize chemotherapy delivery
- **ImmunePrep™** to optimize delivery of immunotherapeutic antibodies

*\*lead therapeutic candidate*

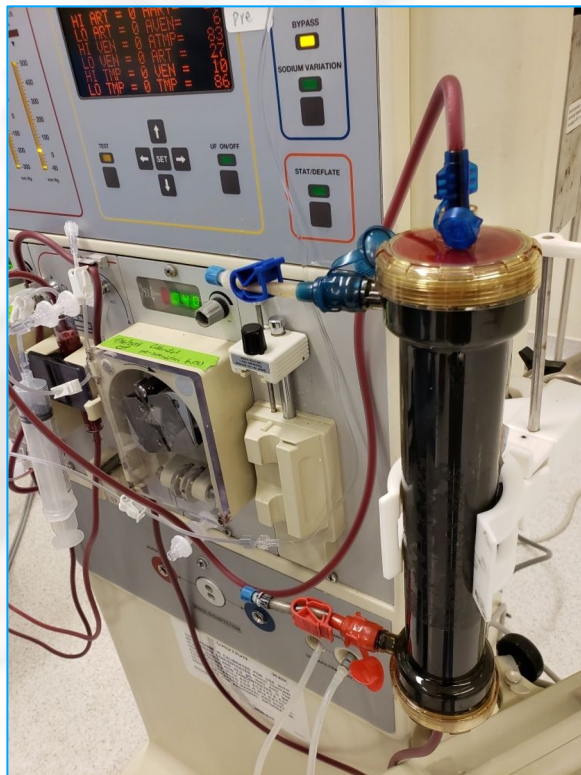




## Previous Blood Purification Achievements

- Oversaw development of first therapy to receive two FDA “Breakthrough Device” designations
- First device approved by FDA under “Emergency-Use Authorization” to treat a viral pathogen
- TIME magazine “Top 25 Invention” and “Top 11 Medical Breakthrough”





*First-in-Mammal Studies at University of Michigan*

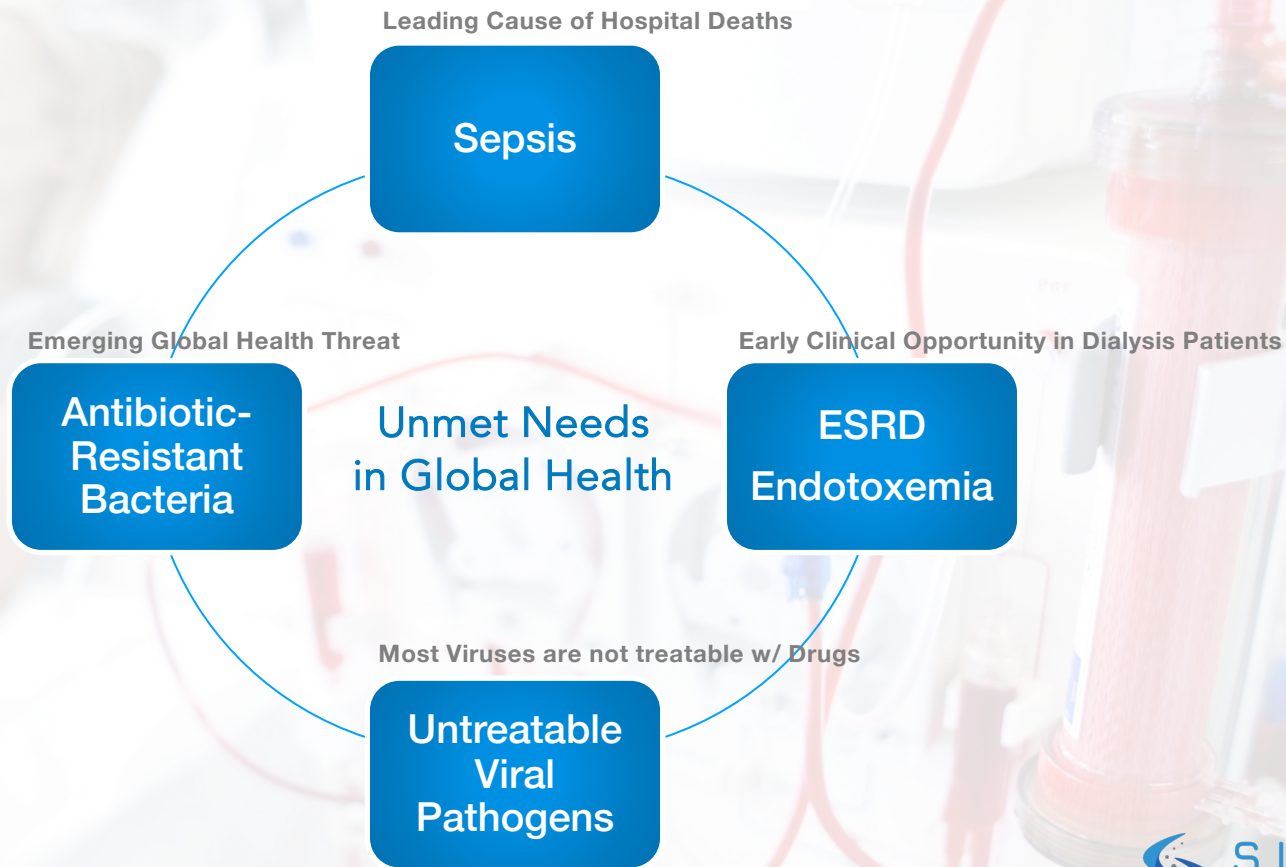
**Sigyn Therapy™**  
Next Generation Technology  
To Address Life-Threatening Infections



## Unprecedented Attributes

- Deployed on dialysis and CRRT machines already located in hospitals and clinics
- Processes the entire bloodstream ~15 times during a 4-hour treatment
- Incorporates a formulation of adsorbent components with ~200,000 sq. meters (~50 Acres) of surface area to adsorb and bind targets
- Isolates viral pathogens, inflammatory cytokines and bacterial toxins (including endotoxin) from the bloodstream







## End-Stage Renal Disease (ESRD) Endotoxemia

- 550,000+ dialysis dependent ESRD patients in the United States
- ~20% annual mortality rate
- Endotoxemia and concurrent inflammation underly early causes of death
- Incidence of endotoxemia is 60-90% (>330,000) in ESRD patients



## Potential Value of Sigyn Therapy to the Dialysis Industry

- Extending ESRD patient lives increases revenues
- Pathway into significant non-ESRD markets



## The Dialysis Industry is Dominated By Two Organizations in North America





- ~200,000 ESRD patients in North American Network
- Average annual revenue per patient is ~\$58,000
- **\$960 million** of increased revenue per month of extended ESRD patient life
- **\$240 million** in recouped revenues per week of reduced hospitalization





- ~208,000 ESRD patients in North American Network
- Average annual revenue per patient is ~\$70,000
- **\$1.2 billion** of increased revenue per month of extended ESRD patient life
- **\$300 million** in recouped revenues per week of reduced hospitalization





## End-Stage Renal Disease (ESRD) Clinical Plan

- Investigation Device Exemption (IDE) drafted for FDA submission
- Enrollment of 12-15 ESRD subjects with endotoxemia and concurrent inflammation at three site locations (Hartford, San Antonio, Las Vegas)
- Sigyn Therapy administered during regularly scheduled dialysis sessions
- Primary endpoint is safety / secondary endpoints includes endotoxin and inflammatory cytokine reduction
- Successful completion sets stage for ESRD pivotal studies and establishes pathway to pursue Sepsis\* studies in non-ESRD subjects (Modular Clinical Design)

*\* ESRD study therapeutic targets underly sepsis and other life-threatening infections*



## About Sepsis

- Leading cause of death in U.S. hospitals\*
- \$38 billion annual cost to the U.S. healthcare system\*
- A dysregulated immune response most often induced by a bacterial or viral infection
- An excessive production of pro-inflammatory cytokines ("the cytokine storm")
- Bacterial toxins that leak from the gut into the bloodstream are potent activators of sepsis

*\* Source: U.S. National Institutes of Health (NIH)*



## Sigyn Therapy™ Sepsis Related Studies\*

- A dysregulated immune response most often induced by a bacterial or viral infection  
*The clearance of viral pathogens from human blood plasma has been validated*
- An excessive production of pro-inflammatory cytokines ("the cytokine storm")  
*The clearance of **TNF alpha, IL-1b and IL-6** has been validated*
- Bacterial toxins that leak from the gut into the bloodstream are potent activators of sepsis  
*The clearance of **peptidoglycan, lipoteichoic acid and endotoxin** has been validated*

\* All studies conducted with pediatric versions of Sigyn Therapy™



## Current FDA Clinical-Stage Device to Treat Sepsis

- The Polymyxin B Hemoperfusion (“PMX”) device reduces the presence of endotoxin in the bloodstream
- PMX is being evaluated in a study of adults treated for endotoxemia and septic shock Study is sponsored by Spectral Medical, who holds the North American rights to PMX.
- As a model for clinical progression-based value, Spectral Medical is a publicly-traded company whose market value is ~16x that of Sigyn Therapeutics



## Oncology

*"We don't develop drugs to treat cancer. We develop devices to improve the benefit of drugs to treat cancer"*





## Chemotherapy

- Most common class of drug to treat cancer
- < 3.5% is delivered to tumor-cell targets
- Off-target chemotherapy contributes to toxicity
- Cancer cells release exosomes that interfere with chemotherapy delivery (chemosomes)





# Sigyn Solution

Associated with a pending patent entitled: *"SYSTEMS AND METHODS TO ENHANCE CHEMOTHERAPY DELIVERY AND REDUCE TOXICITY"*

## ChemoPrep™

- Pre-treatment depletion of chemosomes to improve delivery of chemotherapy to cancer cell targets
- Therapeutic objective to maintain chemotherapy effectiveness with lower doses (toxicity reduction)

## ChemoPure™

- Post-treatment clearance of off-target chemotherapy to further mitigate treatment toxicity



## Immunotherapeutic Antibodies

- Top selling drugs to treat cancer
- Most valued assets in global medicine based on 2023 & 2024 M&A activity
- Over 1000 human studies, yet no effective strategy to improve delivery





## Limitation of Immunotherapeutic Antibodies

- ~2% of doses reach intended cancer cell target
- Delivery intercepted by circulating decoys that display the binding site receptor of the antibody
- Most patients don't respond to therapy





# Sigyn Solution

Associated with a pending patent entitled: *"DEVICES FOR ENHANCING THE ACTIVITY OF THERAPEUTIC ANTIBODIES"*

## ImmunePrep™

- Platform to incorporate a therapeutic antibody to sweep decoys from circulation prior to the infusion of the antibody into a cancer patient
- Simultaneous clearance of the antibody's therapeutic target to further enhance patient benefit without added drug toxicity
- Expanding the use of therapeutic antibodies and enhancing their benefit would provide strategic value to the drug industry



A close-up photograph of a medical device, likely a dialyzer or filter, featuring a clear plastic body and a red top cap. A red tube is connected to the top, and a clear tube with a yellow connector is attached to the side. The background is blurred, showing more of the device and tubing.

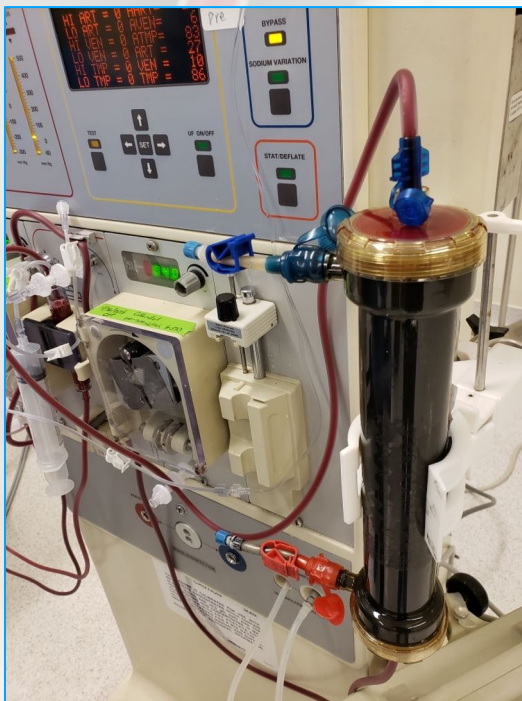
## Conclusion





## Blood Purification Technologies to Treat Cancer & Life-Threatening Infections





*"Sigyn Therapy in Action"*

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- Our pipeline is comprised of first-in-industry devices to improve delivery of leading cancer therapies



## Public Market Data

- OTCQB: SIGY
- 52-Week Range: \$3.00 - \$7.96
- Shares Outstanding: 1,605,377
- >90% of Shares Outstanding are held by management, two funds, and one investment group



## Finance & Marketing Plan

- **2025 Q1:** \$3.75 million Reg D 506c offering of 10% convertible notes<sup>1</sup> (offering documents now available)
- **2025 End of Q1:** Launch of media & investor relations program
- **2025 Q2:** Initiation of \$20 million Regulation A+ uplist to Nasdaq<sup>2</sup> offering

<sup>1</sup>The Company previously raised ~\$5 million through 10% convertible notes whose average conversion price was \$6.75 per share

<sup>2</sup>The Company has submitted listing application to Nasdaq, but there is no assurance the Company will achieve the listing requirements for its shares to trade on Nasdaq





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